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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/088,951	06/02/1998	MARTIN A CHEEVER	920010.535	2326

500 7590 03/09/2004

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EXAMINER	
CANELLA, KAREN A	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/088,951	CHEEVER ET AL.	
	Examiner	Art Unit	
	Karen A Canella	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) 9,11 and 12 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) 9, 11, 12 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. After review and reconsideration, the finality of the previous Office action is withdrawn.

2. Claims 1 and 7 have been canceled. Claims 9, 11 and 12 have been amended.

3. The text of sections of Title 35 US Code not found in this action can be found in a prior Office Action.

4. Claims 9, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carson et al (US 5,679,647, cited in a previous Office action) in view of Lau et al (US 6,080,409, cited in a previous Office action).

Claim 9 is drawn to a method of eliciting or enhancing a T cell response to a human self tumor antigen comprising immunizing a human being with a composition comprising a protein or portion thereof with an amino acid sequence native to a non-human source, wherein the non-human protein or portion thereof has at least 80% amino acid sequence homology to the human self tumor antigen but is not identical in amino acid sequence to the human antigen, and wherein the human self tumor antigen is human prostatic acid phosphatase (PAP). claim11 embodies the method of claim 9 wherein the composition further comprises a pharmaceutically acceptable carrier or diluents.. Claim 12 embodies the method of claim 9 wherein the composition further comprises an adjuvant.

Carson et al teach a method for the induction of tumor associated antigen-specific cytotoxic T-lymphocytes (section III beginning on column 21, line 18 to column 30, line 32). Carson et al teach that T-lymphocyte tolerance to self-antigens in more effectively broken through co-immunization of the host with polynucleotide encoding self antigens and foreign antigens that resemble self antigens , and therefore to optimize the breakdown of T-lymphocyte tolerance to a tumor associated antigen in the host, the host will be preferentially immunized to express homologous and heterologous tumor associated antigens (column 29, lines 56-64). Carson et al teach tumor associated antigens from a species other than the host species (which are immunologically similar to the tumor associated antigens present on tumor cells in the host species) are heterologous tumor associated antigen mimics in addition to synthetically modified

self-antigens which are homogeneous tumor associated antigen mimics (column 27, lines 6-13). Carson et al teach how to modify and select mimic antigens which stimulate T-lymphocyte responses (column 26, lines 9-30). Carson et al teach that the method of the invention could be applied to generate CTL against tumor associated antigens on cells of the intact tumor as well as residual cancer cells (column 21, lines 34-41). Cason et al teach a method wherein the host is co-immunized using a vector encoding an immunostimulatory cytokine (claim 10), thus fulfilling the specific embodiment of claim 12 specifying and adjuvant. Carson et al teach that examples of tumor associated antigens are prostate specific transmembrane protein (column 21, lines 44-48). Carson et al do not teach prostatic acid phosphatase as a tumor associated antigen.

Laus et al teach that prostatic acid phosphatase is a tumor associated antigen (column 4, lines 11-13). Laus et al teach that there is no evidence in the literature that PAP by itself might serve as an inducer and target of CTL (column 6, line 66 to column 7, line 1). Thus, Laus et al teaches the negative limitation of claim 9 specify that the protein or portion thereof is not identical to human prostatic acid phosphatase. Laus et al teach a method of stimulating cytotoxic T-cell responses comprising inducing prostate carcinoma specific cytotoxic T-lymphocytes by prostatic acid phosphatase-GM-CSF pulsed antigen presenting cells (column 14, example 4). Laus et al do not teach the administration of a protein having at least 80% identity.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to substitute the polynucleotide encoding prostatic acid phosphatase for the polynucleotide encoding prostate specific transmembrane protein in the method taught by Carson et al One of skill in the art would have been motivated to do so by the teachings of Carson et al regarding the necessity of immunizing with an tumor associated antigen mimic rather than the tumor associated antigen itself in order to avoid or break the induction of tolerance to the tumor antigen which is a self antigen; and further by the teachings of Laus regarding the expectation that the administration of PAP in an unaltered form would not result in anti-tumor immunity. One of skill in the art would be motivated use a heterologous tumor associated antigen mimic or recombinantly produce a homologous tumor associated antigen mimic in order to elect or enhance a T cell response against PAP.

Applicant argues that Carson et al provides no evidence that a foreign protein alone can activate an autoimmune T cell response. This has been considered but not found persuasive.

The instant claims do not exclude the co-administration of the unmodified tumor associated antigen. Further, the instant specification teaches on page 10, lines 21-22 that " a foreign protein or peptide or both may be used in combination with a human self tumor antigen". Applicant argues that the teachings of Laus et al provide not motivation with a reasonable expectation of success to generate an autoimmune T cell response to PAP using applicants claimed method. This has been considered but not found persuasive. Laus et al teach that there is not expectation that the administration of PAP alone would produce an immune response. Carson et al teach that it is necessary to administer proteins from tumor associated antigens from a species other than the host species (which are immunologically similar to the tumor associated antigens present on tumor cells in the host species) or administer recombinantly engineered homologous tumor associated antigen mimics in order to over come or break tolerance to the tumor associated antigen and generate cytotoxic T lymphocytes which cross react with cell bearing the "self" tumor associated antigens.

5. All other rejections and objections as set forth in the previous Office action are withdrawn.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10 a.m. to 9 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571)272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella,Ph.D.

Primary Examiner, Art Unit 1642

03/05/04

KAREN A. CANELLA PH.D
PRIMARY EXAMINER